DIA

Regulatory Submissions, Information, and Document Management Forum

Primer: February 9 | Short Courses: February 10 | Conference: February 10-12
Bethesda North Marriott Hotel and Conference Center | North Bethesda, MD

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Overview

DIA's *Regulatory Submissions, Information, and Document Management Forum* provides the elements needed to meet the challenges of optimizing the efficient use of regulatory information: the Regulatory Information Management (RIM) principles, effective information management processes and tools, current regulatory and submission requirements, best submission practices, and content management process and system alignment with RIM. With four tracks and daily health authority plenary sessions, you can mix and match sessions to make the best agenda to fit your needs!

Who Should Attend?

Professionals involved in:

- Regulatory Affairs and Operations
- Regulatory Information Management
- Submissions and Global Submissions Management/Project Management
- Medical, Technical, and Regulatory Writing
- TMF and eTMF Management
- Informatics/Bioinformatics Professionals
- Clinical Data/Data Managers
- Information Technology and Support Personnel
- Document and eRecords Management/Specialists
- Essential Document Process and Business Systems
- Regulatory Standards Implementation Specialists and Associates
- Clinical Operations and Processes
- Quality Management
- Quality Assurance/Quality Control and Compliance Professionals
- Strategic Planning and Operations
- Contract Researchers and Service Support Providers
- Emerging Pharmaceutical/Biotech/Device Professionals
- Vendor Relationship Management

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- **Channels:** Keep the conversation going by utilizing these new Track Channels for RSIDM. It's a virtual discussion board for all the topics or questions you have regarding all the tracks at RSIDM. Select Channels on the App Menu to access all the track discussion boards
- **Q&A:** Have a question you would like to see answered live during one of our two Ask the Regulator sessions? Submit your questions by selecting the Question & Answer icon in the bottom toolbar. Select the session where you would like to ask your question and type. You can also submit anonymously – just select that option on the question menu before submitting. Your questions will be stored, reviewed by the panel, and potentially answered live in session!
- **Evaluations:** We value your feedback and are always looking to improve the RSIDM Forum Access the evaluations by selecting General Information in the App Menu. From General Information select Evaluations button.

Not sure about how to use the App? Join us before the Opening Session Monday, February 10 at 12:40PM in Ballroom E-H for a brief tutorial.

SAVE THE DATE!

Regulatory Submissions, Information, and Document Management Forum

February 8-10, 2021

Bethesda North Marriott Hotel and Conference Center

Register today by visiting
DIAglobal.org/RSIDM21

Schedule-At-A-Glance

Track* Key: **Track 1:** RIM Business **Track 2:** RIM Technology **Track 3:** Electronic Document Management (EDM) **Track 4:** Electronic Regulatory Submissions (ERS) **See track descriptions on seperate sheet in your folder.*

PRIMER | SUNDAY, FEBRUARY 9		ROOM
9:30-10:00AM	**Regulatory Content and Submission Primer Registration** **Primer requires an additional registration fee.*	Forest Glen Foyer (Lower Level)
10:00AM-5:00PM	Regulatory Content and Submissions Primer: Content from Authoring Through Archive	Forest Glen (Lower Level)

DAY ONE | MONDAY, FEBRUARY 10		ROOM
7:30-8:30AM	**Short Course Registration** **Short Courses require an additional registration fee.*	Ballroom Foyer (Upper Level)
8:30AM-12:00PM	**Short Course 1:** Data at the Heart of Life Science Professionals: Instant Informed Decision-Making	Brookside (Lower Level)
8:30AM-12:00PM	**Short Course 2:** Preparing and Submitting Standardized Study Data to FDA, Presented by FDA, CDER	White Flint (Lower Level)
11:00AM-5:25PM	Forum Registration	Ballroom Foyer (Upper Level)
12:40-1:00PM	DIA Mobile App Tutorial	Ballroom E-H
1:00-1:25PM	**Welcoming Remarks and Presentation of the Excellence in Service Award**	Ballroom E-H
1:25-2:00PM	**Session 1:** Keynote Address: A New Passion to Life: Experiencing the Impact of Regulatory Submissions	Ballroom E-H
2:00-2:45PM	Refreshment and Networking Break in the Exhibit Hall	Ballroom A-D
2:45-4:00PM	**Session 2:** FDA Plenary	Ballroom E-H
4:10-5:25PM	**Session 3:** Artificial Intelligence Panel: Regulatory Affairs in the Age of Artificial Intelligence	Ballroom E-H
5:25-6:30PM	Networking Reception in the Exhibit Hall	Ballroom A-D
5:45-6:30PM	Speed Networking Hosted by the DIA Diversity in Life Sciences Community	Ballroom Foyer

DAY TWO | TUESDAY, FEBRUARY 11		ROOM
7:30AM-5:30PM	Registration	Ballroom Foyer
7:30-8:30AM	Networking Breakfast in the Exhibit Hall	Ballroom A-D
8:30-9:45AM	**Session 4:** FDA: Digital IND Safety Reporting	Ballroom E-H
9:55-10:45AM	**Session 5:** FDA - Ask the Regulators: Electronic Submissions and eCTD Panel	Ballroom E-H
10:45-11:15AM	Refreshment Break in the Exhibit Hall	Ballroom A-D
11:15AM-12:30PM	**Session 6:** BREAKOUT SESSIONS	
	Track 1: RIM Reference Model: 2019 Progress/Call for Engagement	Ballroom FGH
	Track 2: Put People and Data First to Make Your Process and Technology Work	White Oak (Lower Level)
	Track 3: Inspection Readiness: TMF Data Quality and Completeness Progress	Brookside (Lower Level)
	Track 4: Regional Adoption of eCTD, the Next Wave (China, Eurasia, Middle East)	White Flint (Lower Level)

12:30-2:00PM	Networking Luncheon in the Exhibit Hall **Solution Showcase Theater** Check out our Solutions Showcase Theater to see quick fire presentations from our vendors!	
12:45-1:45PM	**Session 6 Track 1 Continued:** RIM Reference Model: 2019 Progress/Call for Engagement	Ballroom FGH
2:00-3:15PM	**Session 7:** BREAKOUT SESSIONS	
	Track 1 and **3:** The Challenges and Benefits of Consolidating Multiple Legacy RIM Systems from Submission Publishing/Global Regulatory to Archival	Ballroom FGH
	Track 2: ICH M11 Clinical Electronic Structured Harmonized Protocol	White Oak
	Track 4: Strategies to Achieve Global Regulatory Operations Excellence	White Flint
3:15-4:15PM	Refreshment and Networking Break in the Exhibit Hall	Ballroom A-D
4:15-5:30PM	**Session 8:** BREAKOUT SESSIONS	
	Track 1: Incorporating Optimization Strategies for Managing the Processes Associated with End-to-End Labeling Operations and Drug/Device Combination Product Management	Ballroom FGH
	Track 2: Driving Process Optimization with Unified RIM	White Oak
	Track 3: Automation in Regulatory Documentation: Alpha to Omega	Brookside
	Track 4: The Value of Vendor Relationships	White Flint
6:30PM	Dinner on the Town	

DAY THREE | WEDNESDAY, FEBRUARY 12		**ROOM**
7:30AM-2:00PM	Registration	Ballroom Foyer
7:30-8:30AM	Networking Breakfast in the Exhibit Hall	Ballroom A-D
8:30-9:45AM	**Session 9:** BREAKOUT SESSIONS	
	Track 1: Proven Techniques in Selecting and Implementing a Regulatory Information Management Solution that Fits Your Organization	Ballroom FGH
	Track 2: Harnessing Digital Technologies to Transform Life Sciences	White Oak
	Track 3: Deciphering 10 Years of Regulatory and Business Documents to Confirm to Information Technology ETL Requirements	Brookside
	Track 4: Quality and Speed to Submission - Process is the Key for These to Coexist!	White Flint
9:45-10:30AM	Refreshment and Networking Break in the Exhibit Hall	Ballroom A-D
10:30-11:45AM	**Session 10:** BREAKOUT SESSIONS	
	Track 1: IRISS Forum – Hot Topics	Ballroom FGH
	Track 2: The Future is Here: Modern Medical Regulatory Documents Enabled by Structure, Standards, and Content Reuse	White Oak
	Track 3: Maintaining Validation of Your Cloud Based Document Management Systems	Brookside
	Track 4: eCTD AdPromo Panel Discussion	White Flint
11:45AM-1:15PM	Networking Luncheon in the Exhibit Hall	Ballroom A-D
1:15-2:00PM	**Session 11:** FDA - Ask the Regulators: International Panel	Ballroom E-H
2:00-2:15PM	Closing Remarks	Ballroom E-H
2:15PM	Forum Adjourns	

Learning Objectives

At the conclusion of this forum, participants should be able to:

- Explain the regulatory electronic submission process from the completion of its upload to the Electronic System Gateway (ESG) through the time the submission is made available to the review team
- Discuss the agency target time frames for the 1) expected submission upload duration(s) and 2) timeframe between key milestones and notifications
- Describe the current required data standards for regulatory submissions and the status of ongoing data standards initiatives
- Describe organizational processes and governance to ensure integrity, quality, and security of regulatory information (data, documents, records)
- Examine the scope and assess the future of data standards, including IDMP, with respect to systems, processes, and master data
- Discuss ways data can be harmonized, integrated, and viewed to provide an end-to-end view of the regulatory information value chain
- Discuss organizational implications related to increasing electronic interactions with stakeholders and health authorities
- Explain ways to improve processes and communication of regulatory activities including communications, end-to-end processes, and integration of systems for document, submission, and records management
- Interpret global health authority regulations and guidances for systems and business processes
- Identify ways in which the integration of data, documents, and knowledge can be leveraged to develop insights and enable better business decisions
- Identify changes in submission-related regulations impacting RIM business processes

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If you would like to receive a statement of credit, you must attend the entire primer, short course, and/or all three days of the forum, sign in each day at the DIA registration desk upon arrival and complete the online credit request process through My Transcript. Participants will be able to download a statement of credit upon successful submission of the credit request. My Transcript will be available for credit requests beginning **Wednesday, February 26, 2020**.

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PRIMER | SUNDAY, FEBRUARY 9 — ROOM

9:30-10:00AM — **Regulatory Content and Submission Primer Registration** — Forest Glen Foyer (Lower Level)
Primer requires an additional registration fee

10:00AM-5:00PM — **Regulatory Content and Submissions Primer:** Content from Authoring Through Archive — Forest Glen (Lower Level)

Instructors
Betsy Fallen, RN, Consultant, BAFallen Consulting, LLC

Daniel Orfe, MS, President and CEO, Regulatory eSubmissions, LLC

These talks are designed to meet the needs of individuals who are either new to biopharmaceutical-based regulated document management, information management, and regulatory submission publishing for authorities or already experienced in one area looking to gain a broader understanding. This Primer will present the full spectrum of the regulatory submission, information and document management arena. Understanding the various steps throughout the life of document components from their authoring, publishing to PDF, assembling into a submission, delivery to regulatory agencies, and ultimately company archival will yield "aha" moments for the attendees of this offering from all functions along the life-span of regulatory content. Ice breakers will motivate and the "Hands-On" exercises will provide the attendees the ability to apply material as the day progresses.

This Primer will educate you as well as prepare you to optimize your RSIDM experience. Hands-on use of the DIAglobal app and roadmap to finding relevant sessions will be shared.

At the conclusion of this primer, participants should be able to

- Describe the benefits of understanding the complete life phases of regulatory content and the impact that decisions in one place along the life path will have at other stages of the process
- Identify key drivers within each of the life phases and potential pros and cons associated with solution choices
- Recognize the needs of the other organizations involved within the lifespan of the regulatory content and fairly assess their concerns in process and procedure decision-making
- Comprehend the newly released regulations, guidelines, and industry best practices and gain an awareness of their impact

DAY ONE | MONDAY, FEBRUARY 10 — ROOM

7:30-8:30AM — **Short Course Registration** — Ballroom Foyer (Upper Level)
Short Courses require an additional registration fee

8:30AM-12:00PM — **Short Course 1:** Data at the Heart of Life Science Professionals: Instant Informed Decision-Making — Brookside (Lower Level)

Instructors
Hans van Bruggen, MSc, Chief Executive Officer and Regulatory Affairs Scientist, Qdossier, The Netherlands

Michiel Stam, Head of Data Management & Regulatory Information Scientist, Qdossier, The Netherlands

Traditionally, data has been kept in custody in primarily in documents. Life Science is moving away from this paper thinking and shifting towards structured data solutions (e.g. XEVMPD, IDMP, SPL, PQ/CMC, GInAS, ePI), with the data to be entered, stored and maintained in a Regulatory Information Management (RIM) System. RIM data actually safeguards the patients by justifying the high quality of consistently produced drugs with an efficient benefit-risk ratio when used in accordance with the prescribing information. When managed correctly, the data continues to fulfill this role as it is used for making informed decisions throughout the life cycle of a product. If not managed correctly, the data can become a source of failure which puts the patient at risk.

The RIM data undergoes a very dynamic continuous change during the product-development and marketing phases. This short course puts the data in the context of the patients in, showing how it can be used by life science professionals to safeguard patients during development and marketing of drugs, in a tool and company agnostic manner. It will touch upon all contributors and consumers of the regulatory information. It will also address dependencies for general capabilities like management of country requirements, data management, document management, and dossier management.

At the conclusion of this session, participants should be able to:

- Assess the definition of reliable information without the need for verification
- Describe the concept of (circular) end-to-end regulatory information management in which transactions of data are not standalone events
- Identify who owns the data, documents, dossiers, where these are generated, and how these can be repurposed without re-work
- Govern data to support interoperability of tools and streamline regulatory processes.

8:30AM-12:00PM **Short Course 2:** Preparing and Submitting Standardized Study Data to FDA, Presented by FDA, CDER — White Flint (Lower Level)

Session Chair
Ethan Chen, MBA, Director, Division of Data Management Services and Solutions, OBI, OSP, CDER, FDA

In this session, FDA, CDER will provide an update on topics focused on metrics and typical issues from received study data. Study Data Standards listed in the FDA Data Standards Catalog are required for clinical and nonclinical studies that started after December 17, 2016 (for ANDA, NDA, and BLA) or December 17, 2017 (for Commercial IND). Through the technical rejection process, FDA can reject an application because of its technical deficiencies, based on the severity of the eCTD validation criteria.

Based on the Technical Rejection Criteria for Study Data (TRC) conformance analysis conducted by FDA on submissions that contain study data that received by the Agency, FDA updated the Study Data Technical Conformance Guide (TCG) and TRC to provide more clarification on the validation criteria. FDA also developed supporting tools to help Industry meet study data requirements, including the Study Data Self-Check Worksheet.

Presenters will demonstrate the use of the fillable Study Data Self-Check Worksheet and illustrate its ability to identify potential rejectable errors prior to submission to FDA. The learning session will also introduce a web application developed by a PhUSE working group that help sponsors create required Simplified TS Files (ts.xpt).

At the conclusion of this session, participants should be able to:

- Recognize FDA requirements for Standardized Study Data Submission
- Analyze the Study Data Technical rejection criteria validation logic
- Utilize tools available for preparing the Study Data submission

How SEND Data Facilitates FDA Review of Nonclinical Study Data
Stephanie Leuenroth-Quinn, PhD, Pharmacologist, Office of New Drugs, CDER, FDA

FDA Study Data Technical Conformance Guidance
Helena Sviglin, MPH, Regulatory Information Specialist, OCS, Office of Translational Sciences, CDER, FDA

FDA Study Data Technical Rejection Criteria and Supporting Tools
Heather Crandall, MA, Operations Research Analyst, OBI, OSP, CDER, FDA

Tools to Help Create the Simplified ts.xpt File
Hanming Tu, MSc, Vice President, IT, Frontage Laboratories, Inc.

11:00AM-5:00PM **Forum Registration** — Ballroom Foyer (Upper Level)

12:40-1:00PM — **DIA Mobile App Tutorial** — Ballroom E-H

The DIA Global Mobile App is designed to enhance your forum experience and prove valuable information in one place. Download today by searching "DIA Global" in your app store. Come and learn first-hand how to navigate and best use this tool while onsite at the forum.

1:00-1:25PM — **Welcoming Remarks and Presentation of the Excellence in Service Award** — Ballroom E-H

Barbara Lopez Kunz, MSc, Global Chief Executive, DIA

Brooke Casselberry, MSRA, Head, Regulatory Information Management, Beigene

Cindy Chiu, Director, Regulatory Affairs Operations & Quality Management, Merck & Co., Inc.

Michelle Charles, BSN, MPharm, Director, Regulatory Affairs, Gene Therapy Program and Orphan Disease Center, University of Pennsylvania

Ron Fitzmartin, PhD, MBA, Senior Informatics Advisor, Office of the Director, CBER, FDA

Excellence in Service Awardee
Sarah Powell, RAC, President, Powell Regulatory Services

1:25-2:00PM — **Session 1:** Keynote Address: A New Passion to Life: Experiencing the Impact of Regulatory Submissions — Ballroom E-H

Ashley Brown, Senior Submission Coordinator, Regulatory Operations, Accenture

Ashley Brown, Senior Submission Coordinator, Regulatory Operations at Accenture, will offer her unique and inspiring insights on the impact of regulatory submission work in getting medications and devices to market for use by patients. Diagnosed in 2018 with Stage 1 PR, ER and HER2 Positive Breast cancer, Ashley began to think about the parallels between her many submissions and those that enabled her access to quality medications and devices during her treatment. Ashley will share her first-hand experience and the new way she looks at the importance of her work in the lives of patients.

2:00-2:45PM — **Refreshment and Networking Break in the Exhibit Hall** — Ballroom A-D

2:45-4:00PM — **Session 2:** FDA Plenary — Ballroom E-H

Session Chair
Ron Fitzmartin, PhD, MBA, Senior Informatics Advisor, Office of the Director, CBER, FDA

The FDA Plenary session is focused on presenting subject matter experts and topics related to the theme of the RSIDM: the organization, submission, and management of regulatory data and information. This session will present updates on: Data Standards, Structured Product Labeling (SPL) exchange format to Fast Healthcare Interoperability Resource format project, and FDA's study data technical rejection initiative.

Update on FDA Data Standard Program
Ray Wang, Data Standards Program Lead, CDER, FDA

Update on SPL to FHIR
G. Scott Gordon, PhD, Senior Health Informatics Officer, OSP, CDER, FDA

Update on Study Data Technical Rejection
Ethan Chen, MBA, Director, Division of Data Management Services and Solutions, OBI, OSP, CDER, FDA

4:10-5:25PM — **Session 3:** Artificial Intelligence Panel: Regulatory Affairs in the Age of Artificial Intelligence — Ballroom E-H

Session Co-Chairs
Jake Doran, Head of Global R&D IT, Bausch Health

Karen McCarthy Schau, Director, Adaptive Monitoring, Vertex Pharmaceuticals

Thomas Noto, Senior Director, Regulatory Operations, Lexicon Pharmaceuticals

In this panel discussion, we will explore how the Regulatory function is positioned in the age of Artificial Intelligence and emerging technologies. From exploring whether it is hype or reality, to evaluating potential use cases, to building business cases, and evaluating organizational readiness for a change of this magnitude; this session will bring together industry leaders to share insight into how Artificial Intelligence will impact Regulatory. As more and more use cases are defined and practical implementation is realized, how will we see the application and impact play out over the next few years?

Panelists:
Christopher Mundy, Global Life Sciences Solutions Lead, Clarivate Analytics

Sheila Mahoney Jewels, MBA, Independent Workforce Advocate, LifeSciHub

Matt Neal, MA, Senior Director, Regulatory Affairs, Atlara Biotherapuetics

Sylva Krizan, PhD, RAC, Global Compliance, Healthcare and Life Sciences, Amazon Web Services

Rob Connelly, MBA, Executive Director, Product Development, Sychrogenix, a Certara Company

Steve Gens, MS, Managing Partner, Gens and Associates, Inc.

5:25-6:30PM — **Networking Reception in the Exhibit Hall** — Ballroom A-D

5:45-6:30PM — Speed Networking Hosted by the DIA Diversity in Life Sciences Community — Ballroom Foyer

Meet interesting peers during this highly interactive "speed networking" activity. Attendees will pair up for five-minute meet and greets, then switch seats to start all over again. This session is hosted by the DIA Diversity in Life Sciences Community, which is dedicated to fostering industry-level dialog in both corporate diversity, as well as diversity in clinical trials. Reminder to all attendees: bring business cards!

DAY TWO | TUESDAY, FEBRUARY 11 — ROOM

7:30AM-5:30PM — **Registration** — Ballroom Foyer

7:30-8:30AM — **Networking Breakfast in the Exhibit Hall** — Ballroom A-D

8:30-9:45PM — **Session 4:** FDA – Digital IND Safety Reporting — Ballroom E-H

Session Chair
Virginia Hussong, Chief, Data Standards Program, CBER, FDA

This session will provide an FDA overview and update on the new FDA Digital IND Safety initiative, which will require industry to submit IND Safety Reports in ICH E2B format directly to FAERS, and no longer within an eCTD submission. Panelists will discuss the related binding guidance for industry and technical conformance guide, including which submission types are included in the requirement, steps FDA has taken to pilot and test the new submission process, and submission pathways sponsors may choose.

FDA's Implementation of Digital IND Safety
Meredith Chuk, MD, Acting Associate Director for Safety, OHOP, CDER, FDA

FAERS II Status Update for IND Safety
Suranjan De, MS, MBA, Deputy Director, Regulatory Science, OSE, CDER, FDA

Safety Reporting Portal Update
Vali Tschirgi, Project Manager, CBER, FDA

9:55-10:45AM — **Session 5:** FDA - Ask the Regulators: Electronic Submissions and eCTD Panel — Ballroom E-H

Session Chair
Ethan Chen, MBA, Director, Division of Data Management Services and Solutions, OBI, OSP, CDER, FDA

Dedicated to sharing the lastet information on new guidances, this session will allow open discussion between the audience and an esteemed panel of regulatory experts. This session provide attendees the opportunity to ask regulators electronic submission process and validation questions. Submit your questions in advance via the Mobile App by selecting "Question & Answer" in the bottom navigation bar or email AsktheRegRSIDM@DIAglobal.org

Please note: due to the high volume of questions, not all will be answered live at the forum

Lina Cong, Regulatory Information Specialist, OBI, OSP, CDER, FDA

LaMisha Fields, IT Program Manager, Electronic Submissions Gateway, OIMT, OC, FDA

Mark Gray, Senior Project Manager, DSS, CBER, FDA

Valerie Gooding, Project Management Officer, OBI, OSP, CDER, FDA

Lisa Lin, Study Data Standards Manager, Office of Director, CBER, FDA

Jonathan Resnick, PMP, Project Management Officer, OBI, OSP, CDER, FDA

Jiang Xu, Business Informatics, OSP, CDER, FDA

10:45-11:15AM — **Refreshment Break in the Exhibit Hall** — Ballroom A-D

11:15AM-12:30PM — **Session 6:** BREAKOUT SESSIONS

Track 1: RIM Reference Model: 2019 Progress/Call for Engagement — Ballroom FGH

Session Chair
V. "Bala" Balasubramanian, PhD, MBA, Senior Vice President, Life Sciences, Orion Business Innovation

Life Sciences companies continue to strive towards effective management of regulatory information. Lack of a common industry reference model hampers investment in RIM solutions and capabilities, leading to delays, rework and in some cases, product recalls. Aligning on a common RIM Reference Model will allow development of capabilities and solutions that will drive speed, efficiency and compliance. The DIA RIM Working Group formed a sub-group to define a RIM Reference Model. This group (made of industry sponsors, product vendors and consulting companies) has been working towards developing the key RIM processes and information model. The objectives of the session are to present the approach in developing the RIM Reference Model and share key deliverables including: definition of functional stakeholders involved in each major process, information flows and inputs/outputs for each major process, high-level conceptual RIM-related information objects and relationships. We will open this session for larger audience participation in the form of round tables to benefit from everyone's insights. The initial draft of the RIM Reference Model is expected to be released by Summer of 2020.

RIM Reference Model: Investigational Products RIM Process Mapping
Donald Palmer, MA, Associate Director, RIM, Regeneron Pharmaceuticals, Inc.

Marketed Products RIM Process Mapping
Cary Smithson, MBA, Director, Digital Transformation and Management, Grant Thornton, LLP

The Building Blocks of the RIM Information Model
Joel Finkle, Associate Director Offering Management Regulatory Innovation, IQVIA

Track 2: Put People and Data First to Make Your Process and Technology Work

White Oak (Lower Level)

Session Chair
Danielle Beaulieu, PhD, Head, Global Regulatory Business Capabilities, Bristol-Myers Squibb

Data is key to RIM systems. Data is why people use RIM systems. Therefore when implementing a new RIM system, it is critical to start with the data and process in mind. Unless you thoroughly understand the data and why users need it, you will not know what you need to design, and critical aspects such as user acceptance/adoption and data quality will not be successful. Understanding people and business process is the first step to understanding how and what data needs to be maintained. Understanding multiple global legacy business processes and transforming these into simplified and harmonized processes with appropriate use of technology, and a clear governance process is critical to a successful implementation. Understanding when other parts of the organization will need to use regulatory information to enable their processes, will impact both data and processes, and this is when the use of master data management becomes critical. This session will bring together 3 speakers who will share their experiences, successes and failures in implementing systems to fully support the future state of regulatory data, to enable data integrity and achieve business excellence.

Data's Great Until it's Not – The Criticality of Governance and Change Management in Regulated Systems
Jamie O'Keefe, Managing Director, O'Keefe Life Sciences, LLC

New Technology is Great, But What About the Data?
Robert Baldry, Assistant Vice President, Genpact Pharmalink

RIM IDMP MDM Data Integrity Approaches
Teginder Singh, MPharm, Senior Director, Regulatory Affairs, Johnson & Johnson

Track 3: Inspection Readiness: TMF Data Quality and Completeness Progress

Brookside (Lower Level)

Session Chair
Joanne Malia, MS, MSc, Director, Clinical Documentation Management, Regeneron Pharmaceuticals

This session will discuss the current industry best practices regarding the Trial Master File (TMF), where we are today, and where we will likely go in the future. The first presentation will discuss where we are as an industry with the TMF, describe current challenges, and advances. The second presentation will discuss a sponsor case study, how they overcame challenges, and their resulting best practices. The third presentation will discuss a TMF Reference Model initiative to overcome challenges in exchanging TMF records between sponsors and their partners, CROs, and other collaborators.

Evolution of TMF: A Case Study to Building a Successful TMF
Vera Buris, MHS, Senior Manager, Quality and Operations, Submission Sciences, Biogen

eTMF-EMS: Faster Content Exchange for Inspection Preparation and Submissions
Ken Keefer, MBA, PMP, Principle Consultant, Keefer Consulting, Inc.

Track 4: Regional Adoption of eCTD, the Next Wave (China, Eurasia, Middle East)

White Flint (Lower Level)

Session Chair
Michelle Charles, BSN, MPharm, Director, Regulatory Affairs, Gene Therapy Program and Orphan Disease Center, University of Pennsylvania

This session will present a "case study" on adopting eCTD in China from both a process and technical perspective. The first presentation will focus on planning for eCTD submissions in China with a focus on the process and technical considerations Sponsors need to account for. This presentation will be followed by a session that will focus on how eCTD submissions in China will be validated and reviewed. The final presentation will focus on additional regions including Eurasia and the Middle East and planning, process and technical considerations for these regions.

Implementation of eCTD in Eurasia and the Middle East
Adair Turner, MSc, RAC, Principle Consultant, Director Regulatory Operations, PharmaLex

eCTD Adoption in China
Jared Lantzy, PMP, Lead Associate, Booz Allen Hamilton

Planning for eCTD in China: Process and Technology Considerations
Dustin Weisman, Technical Design Expert, Novartis

12:30-2:00PM

Networking Luncheon in the Exhibit Hall

Solution Showcase Theater
Check out our Solutions Showcase Theater to see quick fire presentations from our vendors!

12:45-1:30PM

Session 6

Track 1: Continued: RIM Reference Model: 2019 Progress/Call for Engagement — Ballroom FGH

Session Chair
V. "Bala" Balasubramanian, PhD, MBA, Senior Vice President, Life Sciences, Orion Business Innovation

The RIM Reference Model presentation during Session 6, Track 1 will continue over the lunch hour, providing a forum for the audience to review, validate and challenge the RIM Reference Model Working Group's deliverables such as RIM process maps and RIM information model. It will also provide an opportunity for participants to discuss the challenges and roadblocks to utilizing RIM as a corporate asset and to share their firsthand experiences overcoming challenges in achieving seamless RIM. Key topics will be selected for review and discussion during the roundtable session. The working group is looking for subject matter experts across sponsors, software vendors, system integrators and others to participate in a rich discussion and to provide their insights on the group's deliverables based on recent experiences with RIM transformation initiatives. Feedback from these discussions will be included into Working Group monthly calls and the next round of deliverables.

2:00-3:15PM

Session 7: BREAKOUT SESSIONS

Track 1 and **3** The Challenges and Benefits of Consolidating Multiple Legacy RIM Systems from Submission Publishing/Global Regulatory to Archival — Ballroom FGH

Session Chairs
Cindy Chiu, Director, Regulatory Affairs Operations & Quality Management, Merck & Co., Inc.

The value of consolidating disparate silo-ed submission management and archive systems into a single centralized process is recognized globally by all biopharma companies. However, organizations are faced with the social and technical challenges alignment often brings. This presentation shares the experience from two different companies with the same goals' perspectives.

Global RIM & Publishing Alignment After M&A
Nicole Cocuzza, MBA, Senior Manager, Regulatory Submission, Allergan

Ronnie Rajkumar, Senior Manager, Regulatory Submissions, Allergan

Implementing a Regulatory Archive Management System and Consolidating Multiple Legacy Local Archive Systems
Marina Nisenzona, MS, Director, Regulatory Affairs, Merck & Co., Inc

Deborah Lahr, Associate Director, Regulatory Content Information Management, Merck & Co., Inc.

Track 2: ICH M11 Clinical Electronic Structured Harmonized Protocol — White Oak

Session Chair
Ron Fitzmartin, PhD, MBA, Senior Informatics Advisor, Office of the Director, CBER, FDA

This Special Session will be an interactive session that will solicit early feedback from the attendees on development of the ICH guideline and template for a harmonized clinical protocol. The speakers will be M1 Expert Working Group speakers including the Rapporteur and Regulatory Chair. They will engage all relevant stakeholders and get early input on important design and content considerations which have been developed by the EWG. Presentations will include the business plan and perceived benefit of this effort expressed by SMEs from regulators and sponsors, high-level design principles, the overall deliverables, status and roadmap to delivery in order to get early input for consideration. Interdependencies with other ongoing ICH efforts and alignment steps will also be presented.

Vivian Combs, MS, Advisor/Process Owner, Clinical Systems and Supply Planning, Eli Lilly and Company

Vaishali Popat, MD, MPH, Associate Director of Biomedical Informatics and Regulatory Review Science OND, CDER, FDA

Ken Sakishima, MD, PhD, MPH, Medical Reviewer, Office of Advanced Evaluation with Electronic Data, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Track 4: Strategies to Achieve Global Regulatory Operations Excellence — White Flint

Session Chair
Kevin Tompkins, MBA, MS, Group Director, Global Lead, Global Dossier Management, Bristol-Myers Squibb

The present global regulatory environment requires companies to be agile, costefficient, and effective in their daily operations. Regulatory operations often deal with tight deadlines, last minute changes, and are pushed to accelerate timelines. In order to achieve successful submissions, operations teams need to leverage teamwork, streamlined processes, and effective planning. Focused strategies that facilitate communication and global operations are the foundation for successful submissions. This session will review suggestions and strategies for building a successful team that can tackle the daily challenges teams face while working towards an efficient future state.

Building a Global Regulatory Operations Team
Paul Miller, MBA, Senior Director, Regulatory Technology, Operations and Filing Excellence, Alnylam Pharmaceuticals

Working Smarter, Not Harder: The Future of Globalization
Olga Valentin-Alfieri, MBA, MSc, RAC, Director, Global Submission Management, Eisai Pharmaceuticals

Resourcing a Reg Ops Team: Which Model Fits Best for You
James Hendry, Head of Global Regulatory Operations, GE Healthcare, Pharmaceutical Diagnostics, United Kingdom

3:15-4:15PM — **Refreshment and Networking Break in the Exhibit Hall** — Ballroom A-D

4:15-5:30PM — **Session 8:** BREAKOUT SESSIONS

Track 1: Incorporating Optimization Strategies for Managing the Processes Associated with End-to-End Labeling Operations and Drug/Device Combination Product Management — Ballroom FGH

Session Chair
Jake Doran, Head of Global R&D IT, Bausch Health

In this session, we will hear from subject matter experts from both industry and service providers and identify and learn about best practices for optimizing the labeling operations capabilities across the life sciences industry. At the heart of the process is the need to have well defined strategies around the

data necessary to ensure compliant processes. In addition to Labeling, we will explore strategies for managing drug/device combination products and how the regulations and requirements associated with these unique products, differ from true medical devices or pharmaceutical processes and procedures.

Impact of RIM Submission Data Quality on the E2E Labeling Process
Wanda Rosado, Global Regulatory Information Management Lead, Bristol Myers-Squibb

Effective Labeling Management Requires a New Mindset - A Strategic Guide to Labeling Process Optimization
Cham Williams, MS, Senior Consultant, CGI

Track 2: Driving Process Optimization with Unified RIM — White Oak

Session Chair
Brooke Casselberry, MS RAC, Head, Regulatory Information Management, Beigene

In this panel session, two regulatory leaders from Viela Bio and Sarepta will join the director of RIM strategy at Veeva to explore how modern RIM technology can streamline regulatory processes like registration tracking, submission management, health authority interactions, submission document authoring, and submission archiving and viewing. In addition, they will talk about the planning that happens in parallel to ensure system adoption following go-live, including change management, training, and procedural document development and updating. Lastly, they will discuss how a modern RIM platform can flex and support regulatory operations as companies enter new markets around the globe.

Christina Kim, Director, Vault Rim, Veeva

Lisa Pitt, PharmD, Head of Regulatory Affairs, Viela Bio

Ryan Hernandez, Director of Regulatory Operations, Radius Health

Michael Sauter, Senior Director, Global Regulatory Operations, Alexion Pharmaceuticals, Inc.

Track 3: Automation in Regulatory Documentation: Alpha to Omega — Brookside

Session Chair
Joanne Malia, MS, MSc, Director, Clinical Documentation Management, Regeneron Pharmaceuticals

This session will discuss current automation and analytics to streamline and enhance quality of documentation for both pre-approval and post-approval activities. The first presentation will discuss how to better design clinical trial protocols and the second presentation will discuss the benefits of automation in Pharmacovigilance aggregate report writing.

Analytic Driven Trial Design: Are We There Yet?
Robert DiCicco, PharmD, Deputy Chief Health Officer, IBM Watson Health

Automation, Efficiency, and Risk Mitigation in Regulatory Aggregate Report Writing
Kristen Mandello, DVM, Executive Sales Consultant, Ennov

Track 4: The Value of Vendor Relationships — White Flint

Session Chair
Peter Terbeek, MBA, Senior Director, Publishing and Submission, Astellas

This session will explore the value of relationships between sponsors and operational service providers. We will consider how core competencies and sourcing strategies influence the type and scope of services needed and what defines success. Productive partnerships can accelerate internal harmonization, standardization efforts, and increase confidence in operational agility by incorporating best practices, broader perspectives, and experiences.

Merck and It's Relationship with Vendors
Adam Bone, Senior Specialist, Regulatory Affairs, Merck & Co., Inc.

Effective Outsourcing of RegOps with a Focus on Global Harmonization and Standardization
Teresa Genthe, MS, Vice President, Regulatory Solutions, Genpact Pharmalink

Alison Buno, MBA, Senior Director, Regulatory Submissions, Abbvie, Inc.

6:30PM **Dinner on the Town**

Traveling on your own or looking to connect with fellow attendees? Visit the DIA Registration Desk to link up for dinner! Sign-up sheets will be provided for various local restaurants. Cost of dinner is the responsibility of the individual attendee.

DAY THREE | WEDNESDAY, FEBRUARY 12 — ROOM

7:30AM-2:00PM **Registration** — Ballroom Foyer

7:30-8:30AM **Networking Breakfast in the Exhibit Hall** — Ballroom A-D

8:30-9:45AM **Session 9:** BREAKOUT SESSIONS

Track 1: Proven Techniques in Selecting and Implementing a Regulatory Information Management Solution that Fits Your Organization — Ballroom FGH

Session Chair
Michiel Stam, Head of Data Management and Regulatory Information Scientist, Qdossier, The Netherlands

Information management has revolutionized the complete gamut of regulatory submission processes and how teams that build or contribute towards developmental and commercial applications conduct their work. In the past decade, the pace of innovation has continued to accelerate, expanding the potential for greater efficiency, enhanced connectivity, and better tools to achieve stronger regulatory compliance. The benefits brought forth by state-of-the-art systems and strong business processes can be achieved by organizations of any size, and in key instances, growing businesses have a distinctive advantage in establishing fit-for-purpose solutions that match organizational structure and operations. This session highlights the significant benefits of implementing integrated solutions and good document management practices at any stage of product development, and best method to ensure the most important industry technological gains of the last 20 years are integrated seamlessly into any organization.

The Missing Link: RIM Assessment Strategies that Get Results
Joel Alvarez, MS, MSc, Global Regulatory Compliance, Operations and Labeling Leader, Bill & Melinda Gates Medical Research Institute

The Human Factor: Untap your Organization's Potential
Milagros Vitor-Butzen, Associate Director, Regulatory Operations and Compliance, Takeda Vaccines, Inc.

Winds of Change: How to Harness People, Process, and Technology to Transform the Status Quo
Dee DeOliveira, RAC, Associate Director, Regulatory Operations, Vertex Pharmaceuticals

Track 2: Harnessing Digital Technologies to Transform Life Sciences — White Oak

Session Chair
V. "Bala" Balasubramanian, PhD, MBA, Senior Vice President, Life Sciences, Orion Business Innovation

This session will provide an overview of how digital technologies are driving change across key life science stakeholder ecosystem, including Government/Health Authorities, sponsors, patients and consumers along with some case studies. We will review some specifics around how to mine structured and unstructured information using data warehouses in the cloud to provide much needed insights in the Life Sciences domain. We will also address common pitfalls and best practices while going into cloud and digital solutions in order to ensure success and avoid failure. Old ways of implementing enterprise applications must be forgotten and new approaches are required to ensure the defined ROI is realized.

Digital, Data, and Technology: Case Studies and Exploration of Organizations Driving R&D Digital Transformation
Kristen Sauter, Director, Global Regulatory Informatics & Analytics, Takeda Pharmaceuticals

Mining Structured and Unstructured Data to Determine Cost Quality Metrics
Vivian Neilly, Solution Architect, Google Cloud

The Secret of Why SaaS Solutions Does Not Deliver the Expected Return on Investment and How to Make Sure Your Project Does
Rune Bergendoff, MSc, Director, Consulting Services, NNIT, Denmark

Track 3: Deciphering 10 Years of Regulatory and Business Documents to Confirm to Information Technology ETL Requirements — Brookside

Session Chair
Cindy Chiu, Director, Regulatory Affairs Operations and Quality Management, Merck & Co., Inc.

Innovation for producing medicines that transform patient's lives is paramount to biotechnology companies. The challenge of how to bring this innovation mind-set to 10 years of regulatory documentation and registration data from multiple sources, has lived through numerous iterations of design with limited people resources. This cloud-based single source system of record with a single data model requires a new ELT and teamwork approach. This panel will discuss the technology, the partnerships, and the daily collaboration that allowed a multi-faceted group to quickly evolve into a team of innovators.

Kelsey Edwards, MS, Manager, Regulatory Information Management, Vertex Pharmaceuticals, Inc.

Juhi Saxena, MSc, Senior Analyst, Business Systems Configuration, Vertex Pharmaceuticals, Inc.

Murthy Koppu, MS, Principal Consultant, fme US, LLC

Track 4: Quality and Speed to Submission - Process is the Key for These to Coexist! — White Flint

Session Chair
Dan Orfe, MS, President and CEO, Regulatory eSubmissions, LLC

Speed to patient is a fundamental concept in the regulatory and submissions world. When crunch time hits, it appears inevitable that the submissions team is asked how to make the submission process move faster and that request typically follows with little budgetary support. Planning for electronic common technical document (eCTD) submissions can seem like a complex and confusing process. Key drivers for speed to submissions are the right building blocks: clear processes and high quality. There are a few critical steps companies need to take to make this process run smoothly. Taking time to ensure submissions are completed properly and formatted correctly, the first time is imperative. If any of these steps are overlooked, submissions can take longer, cost more, and impact future lifecycle submissions. This session will evaluate and discuss the importance of quality improvement programs in regulatory departments. Best practices for tracking metrics will be reviewed. Acknowledging the difficulties of implementing change, effective change management strategies that allow regulatory departments to work through process changes will be explored. The advent of AI and how it is affecting (if at all) regulatory groups will be examined.

Six Keys to Successful eCTD Regulatory Submission
Laurie Henricks, Managing Director, Regulatory Submissions Operations, Cardinal Health Regulatory Sciences

Speed to Submission: Process and Quality
Sandra Krogulski, MA, Associate Director, Submission Management, Bristol-Myers Squibb

9:45-10:30AM **Refreshment and Networking Break in the Exhibit Hall** — Ballroom A-D

10:30-11:45AM

Session 10: BREAKOUT SESSIONS

Track 1: IRISS Forum – Hot Topics

Ballroom FGH

Session Chair
Sue Metz, President and CEO, IRISS Forum

This session will discuss the follow hot topics:

Devices: IMDRF TOC implementation pros, cons, implications for document management, EUDAMED, and UDI implementation in EU.

Implications for RIM: How RIM is viewed differently for device companies vs. pharmaceutical companies.

China-4-China: With promising and increasing trends in the China pharmaceutical industry, CFDA reform and China as ICH membership there is an exciting new opportunity to build a Regulatory Operations network of expertise across this newly forming local industry. This presentation will highlight the China challenges, the opportunities which exist, and how IRISS and key local regulatory leaders are working to accelerate industry knowledge and readiness for regulatory reform.

Dynamic Dossiers: Leveraging the foundation technology already in place and complementing it with emerging technology, such as data extraction and visualization technologies, driven through advanced intelligent business process management, the ability to generate submissions in real time will not be just wishful thinking. A successful development of this model will allow global health authorities to reach into sponsor systems to review information in real time while ensuring the intellectual property of the sponsors is maintained without question. This is a much different model from the current submission model of document collection, publishing, packaging, and physical dispatch (whether paper or electronic) for the review process, but the future of data driven process is now a possibility with the right application of technology and global influence.

IRISS Forum – Hot Topics
Chris Mureithi, Manager, Regulatory Information, Parexel

China-4-China
Cesar Vinces, eSub Strategy and Innovation Lead, Pfizer, Inc.

Dynamic Dossiers
Jake Doran, Head of Global R&D IT, Bausch and IRISS Board Co-Chair, IRISS FORUM

Track 2: The Future is Here: Modern Medical Regulatory Documents Enabled by Structure, Standards, and Content Reuse

White Oak

Session Chair
Stacy Tegan, Senior Program Manager, TransCelerate Biopharma, Inc.

This session explores the emerging "new normal" of medical Regulatory documents through implementation of structured authoring to improve comprehension and reuse, application of technology to structured content for speed and quality, and a look at a modernized clinical study report.

Content is Still King: Benefits and Lessons Learned from Implementation of Structured Authoring in Clinical Development
Vyvyca Walker, PhD, MS, Scientific Communications Consultant, Eli Lilly and Company

Living the Dream: Reusable Content in Action
Mitzi Allred, PhD, Director Clinical Operations; Head, Clinical Content Standards, Merck & Co., Inc.

CSR Now Stands for "Concise Study Reports" - Less Really Is More
Kelly Lengyel, MS, Director, Global Medical Writing, Regulatory Affairs, Allergan

Track 3: Maintaining Validation of Your Cloud Based Document Management Systems

Brookside

Session Chair
Karen McCarthy Schau, Director, Adaptive Monitoring, Vertex Pharmaceuticals

Companies must use an effective and agile strategy to manage new releases in order to maximize the value of a cloud-based document management system. The session will be an interactive audience participation regarding the identification of the major pain points associated with maintaining a cloud-based system in a validated state as new releases and features are provided by the vendor. The panelists are industry experts on Regulatory, Clinical and Quality Document Management System who will describe the best practices their companies use to assess the impact of the new release. Topics of discussions will include: analysis, planning, configuration, customization, and testing. A major aspect of the new release is the impact of the changes on business operations.

Maintaining Validation of Your Cloud Based Document Management Systems
Michael Agard, MS, RPh, Senior Consultant, CGI

Maintaining Validation of Your Cloud Based Document Management Systems – eTMF from Business Perspective
Jamie Marie Toth, MS, Director, Head of TMF Operations, Daiichi Sankyo, Inc.

Managing Cloud Platforms Across Stakeholders - Platform vs Module Features
Jamie O'Keefe, Managing Director, O'Keefe Life Sciences

Track 4: eCTD AdPromo Panel Discussion — White Flint

Session Chair
Thomas Noto, Senior Director, Regulatory Operations, Lexicon Pharmaceuticals

The FDA AdPromo eCTD Guidance was finalized in June 2019 and becomes mandatory in June 2021. Although the guidance has been out for more than four years, many companies haven't switched this process to eCTD. Commonly heard excuses are that it is complicated, expensive and just too hard to change a process that entails hundreds of submissions a year per marketed product. This session will be an informative and fun panel discussion with season experts who have made the switch to submitting AdPromo materials in eCTD format within their own companies... and lived to tell about it.

Thomas Noto, Senior Director, Regulatory Operations, Lexicon Pharmaceuticals

Heather Fisher, MS, Senior Manager, Regulatory Operations, Arivis, Inc.

Robert Labriola, MS, Senior Director, Regulatory Services, Synchrogenix

11:45AM-1:15PM — **Networking Luncheon in the Exhibit Hall** — Ballroom A-D

1:15-2:00PM — **Session 11:** FDA - Ask the Regulators: International Panel — Ballroom E-H

Session Chair
Mark Gray, Senior Project Manager, DSS, CBER, FDA

This session provides attendees the opportunity to ask global regulators electronic submission and standardized data questions, including the regulators coordination strategy on the various initiatives. Submit your questions in advance via the Mobile App by selecting "Question & Answer" in the bottom navigation bar or email AsktheRegRSIDM@DIAglobal.org

Please note: due to the high volume of questions, not all will be answered live at the forum

Craig Anderson, Senior Expert, Program Delivery, Health Canada, Canada

Ken Sakushima MD, MPH, PhD, Medical Reviewer, Office of Advanced Evaluation with Electronic Data, Pharmaceuticals, and Medical Devices Agency (PMDA)

Norman Schmuff, PhD, Associate Director for Science, Office of Pharmaceutical Quality, Office of Process and Facilities, CDER, FDA

Ta-Jen Chen, MS, MBA, Project Management Officer, OSP, CDER, FDA

2:00-2:15PM — **Closing Remarks** — Ballroom E-H

2:15PM — **Forum Adjourns**

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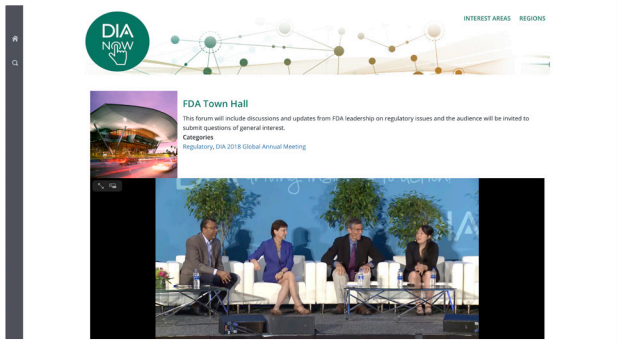

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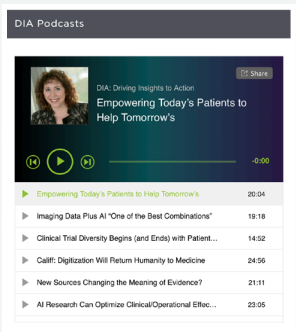

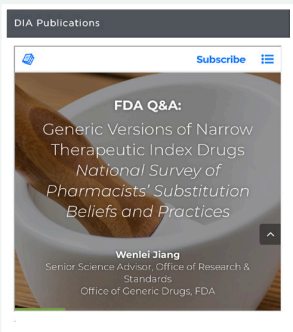

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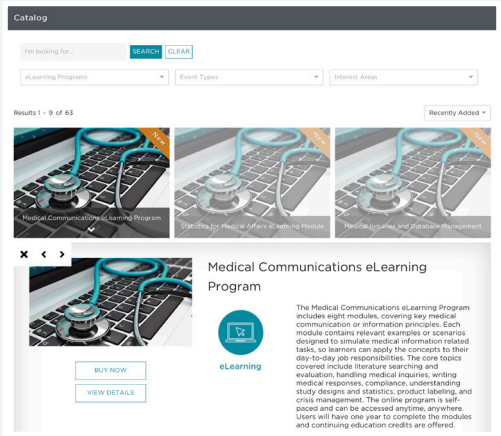

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